K090079

510(k) Summary

as required by CFR section 807.92(c)

MAY - 1 2009

I. General Information

Date: December 23, 2008

Applicant: Progeny, Inc.
675 Heathrow Dr.
Lincolnshire, Ill.
60069

Contact Person: Alan Krema

Telephone: 847-415-9800

Fax: 847-415-9800

II. Names

Device Name:

Trade Name: Vivid
Common Name: Intra Oral Camera System
Classification Name: Intraoral Video Camera

III. Predicate Devices

Gendex EZ CAM
Schick USB CAM

IV. Product Description

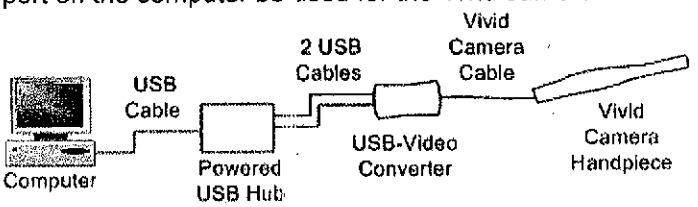
The Progeny, Inc. Vivid Intraoral Video Camera is a state-of-the-art dental video camera. When used with a compatible software application, the operator will be able to capture and store video images into a patient's file.

The Progeny, Inc. Vivid Intraoral Camera System consists of the following main components:

System Configurations

The Vivid Intraoral Video Camera is intended to be connected to a USB hub that is connected to a computer's USB port or to be directly connected to a computer's USB ports.

Connecting the Vivid camera using a USB hub requires that only one USB port on the computer be used for the Vivid camera.



Components List

Part Number	Description
40-A0002	Handpiece, Vivid USB Camera
40-A0003	USB Video Converter
40-08010	Vivid Camera Cable and Handpiece Connector
40-08030	Vivid Camera Cable and Handpiece Connector
40-08003	USB Cable
40-07001	USB 4-port Hub
195-059	Color Chart
00-02-1591	Installation and User Manual CD ROM
40-S0006	Sheath package
40-A2005	Wall Mount Holder
40-A2006	Monitor/Delivery Unit Holder

V. Indications for Use / Rationale for Substantial Equivalence

The Vivid Intraoral Video Camera is intended to provide a dentist with the ability to view the oral cavity prior to and subsequent to dental procedures. The Vivid shares the same indications for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed in section III of this summary.

There are several major independent manufacturers of Intraoral Video Camera Systems on the U.S. market. One is the Gendex EZ CAM. The 510(k) number is K032904 . The classification of this device is listed as product code EIA.

The other currently marketed device is the SCHICK USB CAM, manufactured by Schick Technologies, Inc. the 510(k) number is K963778. The classification of this device5 is listed as product code EIA .

Labeling for the currently marketed devices is included as Appendix B.

Comparison Table:

Characteristic	Schick USB CAM	Gendex EX CAM	Progeny Vivid
Image sensor	¼ in. CCD	1/3 in. CCD	¼ in. CCD
Video output	USB full motion video	NTSC video	NTSC video
Pixel Area	659 x 494	768 x 494 NTSC	768 x 494 NTSC
Focus Range	8 – 40 mm	10 – 50 mm	7 – 50 mm
PC Interface	USB 1.1	USB 2	USB 2
PC Compatibility	MS Direct X video	MS Direct X video	MS Direct X video
Light Source	LED	LED	LED
Integrated Frame Capture Button	YES	YES	YES

VI. Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:

Performance testing and verification to meet product specifications.
Same indications for use as predicate devices.
Certification to Safety Standards.

All of the above steps and evaluations combine to demonstrate that the Vivid Intraoral Video Camera System is safe and effective when the device is used as labeled.

VII. Conclusion

The Progeny, Inc. Vivid Intraoral Video Camera System is determined to be substantially equivalent to the predicate devices, the Gendex EZ CAM, and the Schick USB CAM. The Vivid shares the same indications for use, materials, design, operational and functional features to the currently marketed predicate devices listed in section III of this summary. The Vivid Intraoral Video Camera System is safe and effective when the device is used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Mr. Alan Krema
Director, Products Development
Progeny, Incorporated
675 Heathrow Drive
Lincolnshire, Illinois 60069

Re: K090079
Trade/Device Name: Vivid Intraoral Video Camera
Regulation Number: 872.6640
Regulatory Class: I
Product Code: EIA
Dated: April 14, 2009
Received: April 17, 2009

Dear Mr. Krema:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090079

Progeny

Vivid Intraoral Video Camera

510k number: K090079

Statement of Indications for Use:

Intended Use for the Progeny Vivid Camera:

The Vivid Intraoral Video Camera is intended to provide a dentist with the ability to view the oral cavity prior to and subsequent to dental procedures.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090079